Leflunomide (Arava®)

This sheet is about exposure to leflunomide in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is leflunomide?
Leflunomide is a medication used to treat the autoimmune condition rheumatoid arthritis. Classed as a DMARD (disease modifying anti-rheumatic drug) it can reduce arthritis symptoms like joint swelling and can slow down joint damage. Leflunomide is available as a generic drug or sold under the brand name Arava®.

The manufacturer advises that people should NOT take leflunomide if they are trying to get pregnant, if they are not actively using birth control to prevent a pregnancy, or if they are already pregnant. However, you should not stop taking any medications without first talking with your healthcare provider.

I am taking leflunomide, but I would like to stop taking it before becoming pregnant. How long does the drug stay in my body?
People eliminate medication at different rates. In healthy adults, it takes about 10 weeks (2 and 1/2 months) on average after the last leflunomide dose for most of the drug to be gone from the body. However, the manufacturer of Arava® says that for some people it could take up to two years for the drug to leave the body. Treatments exist to help get leflunomide out of the body. Talk with your healthcare providers about the blood test to check levels and treatments to remove the medication from your body.

I take leflunomide. Can it make it harder for me to get pregnant?
Animal studies done by the manufacturer did not find that leflunomide made it more difficult to get pregnant. However, people who are trying to get pregnant should not be taking leflunomide.

Does taking leflunomide increase the chance for miscarriage?
Miscarriage can occur in any pregnancy. For people who become pregnant while on leflunomide, the results from human data has not suggested an increased chance of miscarriage.

Does taking leflunomide in the first trimester increase the chance of birth defects?
Every pregnancy starts off with a 3-5% chance of having a birth defect. This is called the background risk.

Animal studies have raised concern that leflunomide could increase the chance for birth defects when treated with the medication at levels like those used to treat humans. Results from case reports, registries and studies in humans have not shown an increased chance of birth defects or a distinct pattern of birth defects from exposure to leflunomide during pregnancy. One small study of 109 people (64 people in the main study and 45 in the case-series study) who became pregnant while taking leflunomide did not find an increased chance of birth defects. Nearly all of the people in the study stopped taking leflunomide very early in their pregnancy, and received the advised treatment to remove the medication from the body once they found out that they were pregnant, which eliminated the drug as quickly as possible from their blood. These factors make it more difficult to draw conclusions about the possible effects leflunomide might have on pregnancies where people had leflunomide in their blood for longer periods of time in pregnancy. Two small studies, where people who did not receive the advised ‘wash out’ treatment that were exposed to leflunomide in the first trimester, did not suggest an increased chance of birth defects.

Does taking leflunomide in pregnancy increase the chance of other pregnancy related problems?
The limited data from a few studies has not supported an increased chance of prematurity (birth before 37 weeks), or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) with the use of leflunomide during pregnancy.

Does taking leflunomide in pregnancy affect future behavior or learning for the child?
Studies have not been done to see if leflunomide can cause behavior or learning issues for the child.

Breastfeeding while taking leflunomide:
There are no studies looking at the use of leflunomide in breastfeeding, which means there is no information on the amount of leflunomide that can get into the breastmilk. Medications with a long-half life (the amount of time for 50% of the drug to eliminate from the body), such as leflunomide, have the potential to build up in the breast milk. In persons who take leflunomide, the medication can weaken the immune system, which leads to some concerns about the possible effects to a nursing infant. The product label for leflunomide recommends people who are breastfeeding not use this medication. Talk to your healthcare provider about all of your breastfeeding questions.

If a male takes leflunomide, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?
One study looked at males who received prescriptions for medications used to treat rheumatoid arthritis. A small number were exposed to leflunomide. Among these no increased chance of birth defects were observed. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

MotherToBaby is currently conducting a study looking at rheumatoid arthritis and the medications used to treat RA in pregnancy. If you would like to learn more, please call 1-877-311-8972 or visit https://motehrtobaby.org/join-study/.

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